REMARKS

The Examiner is thanked for the telephone interview courteously granted to the undersigned, in connection with the above-identified application. Prior to the interview, the undersigned provided the Examiner with proposed amended claims 3, 4 and 7 for discussion during the interview. These proposed amended claims 3, 4 and 7 further defined the pH; moreover, claims 4 and 7 were further amended to recite content of each of specified free amino acids formed, while claim 3 was further amended to recite that the amino acids were "free" amino acids; and each of claims 3, 4 and 7 was further amended to recite that each of the contents of amino acids was an amount of the amino acid released into water from 100g of the food ingredient by autolysis reaction. The undersigned indicated during the interview that claims directed to the food ingredient would be cancelled without prejudice or disclaimer.

Based upon these proposed amended claims 3, 4 and 7, each of the rejections in the Office Action mailed May 25, 2010 was discussed. Initially, it was pointed out that "two-row barley" in the present claims was appropriate, in that there had been a translation mistake in the above-identified U.S. application from the PCT application in setting forth "malting" barley, rather than two-row barley. It was also pointed out to the Examiner as to the meaning of units of mg/100g for contents of the various amino acids; and the meaning of "60% flour" as in, for example, proposed amended claim 7, was discussed. In connection with the prior art rejections, differences between the subject matter of, for example, claims 3, 4 and 7 as submitted to the Examiner before the aforementioned interview, and the teachings of the applied prior art, were discussed, and it was pointed out to the Examiner that

such differences achieved advantages according to the present invention. No agreement was reached during this interview.

Applicants have amended their claims in order to further clarify the definition of various aspects of the present invention, in light of, inter alia, discussions during the aforementioned interview. Specifically, Applicants have amended their claims to cancel all claims directed to the food ingredient, without prejudice or disclaimer (that is, claims 1, 2 and 9-12 have been cancelled without prejudice or disclaimer). In addition, claim 7 has been cancelled without prejudice or disclaimer.

In addition, the subject matter of claim 13 has been incorporated into each of claims 3 and 4; and, correspondingly, claim 13 has been cancelled without prejudice or disclaimer. Claims 3 and 4 have been further amended to recite that the recited processing therein provides a mixture of amino acids in the water, with claim 4 being further amended to recite a content of each of specified free amino acids in the mixture of amino acids; claim 3 has also been amended to recite a content of specified "free" amino acids in the mixture of amino acids. Each of claims 3 and 4 has been further amended to recite that the content of each amino acid is an amount of the amino acid released into water from 100g of the food ingredient by autolysis reaction.

In connection with amendments to claims 3 and 4, note, for example, the first full paragraph on page 5 of Applicants' amended specification submitted August 23, 2006.

Applicants are also adding new claims 14-21 to the application. Claim 14, dependent on claim 4, recites that the immature seed is a seed 4-5 weeks after heading; and claims 15 and 16, each dependent on claim 4, respectively recites that the food ingredient is in a form of an aqueous solution, and recites that the food

ingredient is in a form of a dry powder, having been subjected to a drying treatment at 110°C or lower. Claim 17, also dependent on claim 4, recites a composition ratio of each amino acid of valine, isoleucine, leucine, arginine and glutamine. In connection with claims 14-17, note, for example, the last full paragraph on page 8; the paragraph bridging pages 10 and 11; and the paragraph bridging pages 11 and 12, of Applicants' amended specification submitted August 23, 2006. Claims 18 and 20, dependent respectively on claims 3 and 4, recite the further step of incorporating the mixture of amino acids in a food; and claims 19 and 21, dependent respectively on claims 3 and 4, recite the further step of incorporating the mixture of amino acids in a drink. Note, for example, the "Industrial Applicability" of the present invention, on pages 23 and 24 of the amended specification submitted August 23, 2006.

It is respectfully submitted that the present amendments are to be entered, notwithstanding the Finality of the Office Action mailed May 25, 2010, in light of the concurrently filed RCE Transmittal; and it is respectfully submitted that the present amendments and Remarks constitute the necessary Submission under 37 CFR 1.114 for this RCE Transmittal.

Applicants respectfully traverse the rejection of claims under the first paragraph of 35 USC 112, as failing to comply with the written description requirement, in view of the enclosed Declaration under 37 CFR 1.132 and the following remarks.

Thus, the enclosed Declaration by Mr. Y. Nogata, the first-named inventor in the above-identified application, points out the translation error in the English translation of the National Stage application from the Japanese of the corresponding PCT application. In particular, note that Mr. Nogata is knowledgeable in both the

Japanese and English languages (see Item 5 on page 2 of the enclosed Declaration), this knowledge being supported by articles written by Mr. Nogata in English. Note especially, Items 9-11 on page 3 of the enclosed Declaration, establishing that "two-row barley" is more suitable as the English translation of the Japanese term used in the original PCT application. In view of the enclosed Declaration, it is respectfully submitted that Applicants have established that the specification of the PCT application clearly supports the term "two-row barley". As the PCT application is the proper description for the above-identified National Stage application, rather than the English translation of the PCT application, it is respectfully submitted that the amendment of the specification and claims of the above-identified application to recite "two-row barley" is proper; and, in particular, it is respectfully submitted that the rejection of claims 1-4, 7 and 9-13 under the first paragraph of 35 USC 112, as failing to comply with the written description requirement, is improper insofar as applicable to the claims as presently in the application. In this regard, it is noted that Applicants' specification clearly discloses "two-row barley", and thus the specification clearly complies with the written description requirement in connection with "two-row barley".

The rejection of claims 1-4, 7 and 9-13 under the second paragraph of 35 USC 112, as being indefinite, set forth in Item 6 on page 3 of the Office Action mailed May 25, 2010, is respectfully traversed, insofar as applicable to the claims as presently in the application. Thus, Applicants have omitted from the present application claims reciting the phrase "60% flour". Accordingly, it is respectfully submitted that the contention by the Examiner that the phrase "60% flour" renders claim 2 indefinite is moot.

In connection with recitation of amino acid content in units of mg/100g, note that claims 3 and 4 recite that the contents of each of the free amino acids is an amount of the amino acid released into water from 100g of the food ingredient by autolysis reaction. It is respectfully submitted that this is not the concentration of amino acid contained in 100g of the food ingredient, but rather is amount of amino acid released into water from 100g of food ingredient (the weight of the food ingredient being based on its dry weight) by autolysis reaction, as can be seen from, for example, the paragraph bridging pages 4 and 5 of Applicants' amended specification. In view of this amendment to claims 3 and 4 to set forth specifics of the units of mg/100g, it is respectfully submitted that the basis for rejection of claims under the second paragraph of 35 USC 112, set forth in lines 4-6 on page 3 of the Office Action mailed May 25, 2010, is moot.

Applicants respectfully submit that all of the claims presented for consideration by the Examiner patentably distinguish over the teachings of the references applied by the Examiner in rejecting claims in the Office Action mailed May 25, 2010, that is, the teachings of U.S. Patent No. 3,716,365 to Walmsley, et al., the publication entitled "Barley Production in Alberta: Harvesting", and the abstract of Korean Patent Document No. 2002062869 of Sung, et al., under the provisions of 35 USC 103.

It is respectfully submitted that these references as applied by the Examiner would have neither disclosed nor would have suggested such a method of production of a food ingredient as in the present claims, including allowing a mixture of bran and shorts obtained by a specified technique to be immersed in water under a condition of a pH of 4.0-5.0 and at specified temperature and time conditions, so as to provide a mixture of amino acids in the water, wherein a content of free

glutamine in the mixture of amino acids is 20-430mg/100g, a content of free valine in the mixture of amino acids is 20-435mg/100g, a content of free leucine in the mixture of amino acids is 15-130mg/100g, a content of free leucine in the mixture of amino acids is 35-435mg/100g, and a content of free arginine in the mixture of amino acids is 25-300mg/100g, with each of the foregoing contents being an amount of the amino acid released into water from 100g of the food ingredient by autolysis reaction. See claim 3.

Furthermore, it is respectfully submitted that the teachings of the these applied references would have neither disclosed nor would have suggested such a method of production of a food ingredient, which includes allowing a mixture of bran and shorts obtained by a specified procedure to be immersed in water under conditions of a pH of 4.0-5.0 at a specified temperature for a specified time, so as to provide a mixture of amino acids in the water wherein a content of free glutamine in the mixture of amino acids is 150-405mg/100g, a content of free valine in the mixture of amino acids is 190-325mg/100g, a content of free isoleucine in the mixture of amino acids is 125-145mg/100g, a content of free leucine in the mixture of amino acids is 350-520mg/100g and a content of free arginine in the mixture of amino acids is 155-260mg/100g, each of the foregoing contents being an amount of the amino acids released into water from 100g of the food ingredient by autolysis reaction. See claim 4.

As discussed in detail infra, and with reference to the teachings of Walmsley, et al., in forming alcoholic beverages such as beer, ale, lager and the like, a brewers' wort has been used; such brewers' wort includes an enzyme system, e.g., containing both protease and α-amylase enzymes together with a malt or malt extract. That is, in Walmsley, et al., enzymes such as protease and α-amylase enzymes have been

externally added, so as to provide the brewers' wort having desired level of sugars. It is respectfully submitted that this reference, either alone or in combination with the teachings of the other references as applied by the Examiner, would have neither disclosed nor would have suggested such a method of production of a food ingredient as in the present claims, wherein amino acids are produced by utilizing an action of protease being endogenously present (autolysis reaction), not by adding protease externally.

That is, as described in the paragraph bridging pages 4 and 5 of Applicants' amended specification, the present inventors have found that when the ground product of the immature seed and mature seed is immersed in water under a certain condition, the protein is decomposed by the action of protease which is endogenously present in high concentration in bran primarily on the external side of the seed, and shorts including germ, and, thus, specific amino acids are released in high concentrations. Due thereto, the presently claimed method provides a mixture of amino acids in the water, having a relatively high content of free amino acids as set forth in the present claims.

Furthermore, it is respectfully submitted that the teachings of the applied references would have neither disclosed nor would have suggested such method of production of food ingredient as in the present claims, having features as discussed previously in connection with claims 3 and 4, and, additionally, wherein the immature seed is a seed 4-5 weeks after heading (see claim 14); and/or wherein the food ingredient is in the form of an aqueous solution (see claim 15), or in the form of a dry powder having been subjected to a drying treatment at 110°C or lower (see claim 16); and/or the composition ratio of each amino acid as in claim 17; and/or

incorporation of the mixture of amino acids in a food (see claims 18 and 20) or in a drink (see claims 19 and 21).

As presently claimed, the above-identified application is directed to a production method of a food ingredient including enriched free amino acids, in particular, a food ingredient having an elevated content of free glutamine, valine, isoleucine, leucine and arginine.

There are four methods of production of an amino acid, i.e., fermentation method, enzyme method, synthesis method and extraction method. Among these, the fermentation method and enzyme method are principally used, and various kinds of amino acids have been industrially produced by either of these two methods.

As the health consciousness of consumers grows, beverages, foods and supplements have been produced with a focus on health nutrition functions of amino acids; and, in particular, an advantage of ingestion of branched chain amino acids such as valine, leucine and isoleucine, as well as glutamine and arginine, has become common knowledge in fields of sports medicine. However, production costs of the branched chain amino acids, glutamine and arginine are comparatively extremely high. Furthermore, production of glutamine and leucine, conventionally, is restricted to use in medical drugs, and a predominant production method of leucine is currently an extraction method which entails high costs.

Against this background, Applicants provide a production method for forming a food ingredient having an elevated content of free amino acids such as branched chain amino acids, glutamine and arginine. As described in the paragraph bridging pages 4 and 5 of Applicants' amended specification, the present inventors have found that when the ground product of the immature and mature seeds of various materials (e.g., wheat or barley) is immersed in water under specified conditions,

protein is decomposed by the action of protease which is endogenously present in high concentration in bran primarily on the external side of the seed, and shorts including germ, and, thus, specific amino acids are released in high concentrations. Thus, a food ingredient can be produced having relatively high contents of free branched chain amino acids, glutamine and arginine, as described in the paragraph bridging pages 23 and 24 of Applicants' amended specification (see also the Examples on pages 12-23 of Applicants' amended specification).

According to the present invention the amino acids are produced by utilizing an action of protease which is endogenously present (that is, an autolysis reaction), not by adding protease externally. According to the present invention, it is possible to elevate the content of the recited amino acids by selectively decomposing an easily decomposable (storage) protein, due only to an action of the protease endogenously present in the (storage) protein in the specified seeds (e.g., immature seed) of wheat or barley.

That is, according to the present invention, the protease endogenously present in the seed is used to elevate amino acid content. It is respectfully submitted that the protease endogenously present has never been noteworthy due to its low activity, and thus has been hardly studied and reported. According to the present invention, and, e.g., through use of the processing according to the present invention, the endogenously present protease can be used to selectively elevate the content of the specified amino acids, accomplishing the objectives of the present invention.

Walmsley, et al. discloses a process for manufacturing a brewers' wort, for use in the manufacture of non-distilled alcoholic beverages such as beer, ale, lager, and the like, as well as an enzyme system for use in obtaining such brewers' wort.

The method is described most generally from column 3, line 50, through column 4, line 14, and includes reacting a ground or milled starch-containing material under defined temperature and time conditions with up to 30%, based on the weight of starch-containing materials, malt or malt extract and discrete protease and α-amylase enzymes in a specified amount; and, subsequent thereto, heating an aqueous slurry of the materials, with a pH adjusted if need be to between about 5.0 and about 6.5, to between about 40° and 55°C for a period of between about 30 and about 120 minutes. See also column 7, lines 23-30, of this patent.

It is respectfully submitted that Walmsley, et al. would have neither taught nor would have suggested such a food ingredient, or such method, as in the present claims, including use of the immature seed of wheat or barley, or use of the mature seed of wheat or barley selected from the group of wheat, two-row barley and naked barley, or content of the various amino acids, as in the present claims, and advantages thereof.

It is emphasized that Walmsley, et al. discloses a beer (and the like) brewing ingredient, as indicated by the Examiner in the second paragraph of Item 10, on page 4 of the Office Action mailed May 25, 2010. It is respectfully submitted that this reference does not disclose, nor would have suggested, use of the specific materials as in the present claims, or content of the various amino acids, as presently claimed.

Walmsley, et al. requires addition of a discrete enzyme mixture of protease and α-amylase enzymes. It is respectfully submitted that with addition of these external enzymes, a different product is formed than that formed according to the present invention; and, specifically, it is respectfully submitted that Walmsley, et al. would have neither disclosed nor would have suggested providing the mixture of amino acids as in the present claims, especially with a content thereof, and

advantages thereof of a relatively high free amino acid content, as in the present invention.

In connection with amino acid content, contentions by the Examiner in lines 3-5 on page 6, and in the last three lines on page 6, of the Office Action mailed May 25, 2010, are noted. Contrary to the contention by the Examiner, it is respectfully submitted that Walmsley, et al. does not disclose a process of making the food ingredient "substantially the same as presently claimed". That is, it is again emphasized that Walmsley, et al. requires addition of protease, as well as addition of α-amylase, enzymes (that is, externally added enzymes). It is respectfully submitted that the process as in Walmsley, et al. is focused on providing a ratio between fermentable and non-fermentable sugars, associated with an acceptable brewers' wort. It is respectfully submitted that the process of Walmsley, et al. as a whole, including the purpose thereof, would have neither disclosed nor would have suggested the presently claimed method, including, inter alia, providing the mixture of amino acids in the water and wherein content of free amino acids in the water is that set forth in the present claims.

It is respectfully submitted that the additional teachings of the secondary references as applied by the Examiner would not have rectified the deficiencies of Walmsley, et al., such that the presently claimed invention as a whole would have been obvious to one of ordinary skill in the art.

The article entitle "Barley Production in Alberta: Harvesting" as applied by the Examiner discloses harvesting of barley, including harvesting of high moisture barley. This article discloses that as an optional management practice, or where late-sown grain may fail to mature, or where poor drying conditions prevail at harvest

time, barley may be harvested when the grain contains 25-35% moisture; and such grain is handled, stored and utilized as high moisture feed grain.

It is respectfully submitted that this article is primarily directed to providing feed grain. Especially in view thereof, it is respectfully submitted that one of ordinary skill in the art concerned with in Walmsley, et al., directed to making brewers' wort, would not have looked to the teachings of the article "Barley Production in Alberta: Harvesting".

In any event, even assuming, arguendo, that the teachings of these references were properly combinable, such combined teachings would have neither disclosed nor would have suggested the presently claimed method, including, inter alia, amino acid content of the mixture of amino acids provided by the immersion under the specified conditions, as in the present claims, and advantages achieved thereby; and/or other features of the present invention as discussed in the foregoing, and advantages thereof.

The Abstract of the Korean patent document discloses a method for manufacturing a healthy food product by immature barley powder prepared by boiling immature barley with loess water and then followed by drying and pulverization.

Even assuming, arguendo, that the teachings of the Abstract of the Korean patent document were properly combinable with the teachings of Walmsley, et al. and of the article "Barley Production in Alberta: Harvesting", such combined teachings would have neither disclosed nor would have suggested the production method of the present claims, including the immersion of a mixture of bran and shorts obtained by a specified method, or of a mixture of bran and shorts obtained from an immature seed of wheat or barley selected from a specified group thereof, in

water under specified conditions, so as to provide a mixture of amino acids in the water having contents of specific amino acids as in the present claims, and advantages thereof; and/or other features of the present invention as discussed in the foregoing, and advantages thereof.

In view of the foregoing comments and amendments, and, moreover, in view of the concurrently filed RCE Transmittal, entry of the present amendments, and reconsideration and allowance of all claims then pending in the above-identified application, are respectfully requested.

To the extent necessary, Applicants hereby petition for an extension of time under 37 CFR 1.136. Kindly charge any shortage of fees due in connection with the filing of this paper, including any extension of time fees, to the Deposit Account of Antonelli, Terry, Stout & Kraus, LLP, Account No. 01-2135 (case 1333.46520X00), and please credit any overpayments to such Deposit Account.

Respectfully submitted,

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